UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

James J. Napoli
Marshall, Gerstein & Borun
233 South Wacker Drive
Chicago, IL 60606

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,859,006

MAR 21 2007

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,859,006, which claims the human drug product CIALIS® (tadalafil), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 679 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 679 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 22, 2006, (71 Fed. Reg. 35919), would be 1,325 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (1,067 - 168) + 876
	=	1,325 days (3.6 years)

Since the regulatory review period began July 29, 1998, before the patent issued (January 12, 1999), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 29, 1998, to and including January 12, 1999, is 168 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,325 days, would extend the patent from January 12, 2016 to August 29, 2019, which is beyond the 14-year limit (the approval date is November 21, 2003, thus the 14 year limit is November 21, 2017). The period of extension is thus limited to 679 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, January 12, 2016, to and including November 21, 2017, or 679 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,859,006

Granted:	January 12, 1999
Original Expiration Date[1]:	January 12, 2016
Applicant:	Alain Claude-Marie Daugan
Owner of Record:	ICOS Corporation
Title:	Tetracyclic Derivatives, Process of Preparation and Use
Product Trade Name:	CIALIS® (tadalafil)
Term Extended:	679 days
Expiration Date of Extension:	November 21, 2017

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: CIALIS® (tadalafil)
FDA Docket No.: 2004E-0413

[1]Subject to the provisions of 35 U.S.C. § 41(b).